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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,503	02/18/2004	Matthew F. Ogle	3126.03US02	2970

62274 7590 03/01/2011

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EXAMINER	
MEHTA, BHISMA	
ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
03/01/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,503	OGLE ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-27 and 47-57* is/are pending in the application.

4a) Of the above claim(s) *48 and 51* is/are withdrawn from consideration.

5)☒ Claim(s) *53* is/are allowed.

6)☒ Claim(s) *20,21,24-26,47,52,54,55 and 57* is/are rejected.

7)☒ Claim(s) *22,23,27,49,50 and 56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION.

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification fails to disclose the medical device being a percutaneous device having surface capillaries associated with a portion of the device to be placed within the patient (claims 20 and 47).

Claim Objections

2. Claims 20-27, 47, 49, 50, 52, and 54-56 are objected to because of the following informalities:

The use of "surface capillaries associated with a portion of the device to be placed within the patient" in lines 10-11 of claim 20 and in lines 10-11 of claim 47 is unclear as to whether the surface capillaries refer to the capillary/capillaries along the outer surface of each of the surface capillary fiber or other surface capillaries associated with a portion of the device to be placed within the patient. For the purpose of examination of the claims, the surface capillaries associated with a portion of the device to be placed within the patient as recited in lines 10-11 of claim 20 and in lines 10-11 of claim 47 will be interpreted to be referring to the capillaries of the outer surface of the surface capillary fibers.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 20, 25, 26, 47, 54, 55, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaughn et al ("Expanded Surface Area Fibers: A Means for Medical Product Enhancement") in view of Deker (U.S. Patent No. 2,972,350).

Vaughn et al disclose a medical device comprising a plurality of surface capillary fibers associated with at least a portion of a surface of the device (as disclosed in line 14 of page 304 to line 20 of page 305 and line 21 of page 308 to line 28 of page 310). See Figure 2. In lines 14-19 of page 304, Vaughn et al disclose the fibers as being polymeric fibers. In lines 1-20 of page 305, Vaughn et al disclose that a quantity of a liquid or other material for predetermined dispensing is pre-loaded and in association with the surface capillary fibers wherein the liquid or other material would be capable of eluting in a controlled way from the fibers when the surface capillary fibers are in contact with a patient's body fluids or tissue. Furthermore, each of the surface capillary fibers comprises at least one capillary along its outer surface running along at least a portion of the length of the surface capillary fiber (lines 1-20 of page 305). In line 21 of page 308 to line 28 of page 310, Vaughn et al disclose that the medical device is a may be any of those listed on page 310 such as absorbent burn pads, bandages with bacteria barriers, medicated wound dressings, surgical sponges, or transdermal wound

dressings. Even though Vaughn et al disclose that a quantity of a liquid or other material for predetermined dispensing is pre-loaded and in association with the surface capillary fibers of the medical device and that the medical device may be a medicated wound dressing or surgical sponge, Vaughn et al are silent on the specifics of the liquid or material being a bioactive agent. It would have been obvious to one having ordinary skill in the art at the time the invention was made that the liquid or other material for predetermined dispensing which is pre-loaded and in association with the surface capillary fibers as disclosed by Vaughn et al would be a medicated or bioactive agent as Vaughn et al disclose that the device may be a medicated wound dressing and thus, the liquid or other material would be a medication or bioactive agent. Even though Vaughn et al disclose that the medical device may be a medicated wound dressing or surgical sponge, Vaughn et al are silent on the specifics of the medical device being a percutaneous device having surface capillaries associated with a portion of the device to be placed within the patient or being an implantable device. Deker discloses a surgical dressing or sponge which is a percutaneous device or an implantable device that is adapted to be used within a patient's body in surgical operations where the dressing or sponge is used for the application of medication within the body (lines 15-41 of column 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made that the device of Vaughn et al is a or is capable of being used as a percutaneous device or as an implantable device as taught by Deker as both Vaughn et al and Deker disclose medical devices such as medicated wound dressings and surgical sponges and Deker discloses that it is well known to use a surgical

dressing or sponge within the body of a patient to apply medication. Using the device of Vaughn et al as a percutaneous device or as an implantable device as taught by Deker would result in the surface capillaries of the device of Vaughn et al being associated with a portion of the device which is placed within the patient. As to claim 25, see lines 1-20 of page 305 and Figure 2. As to claim 26, the device is configured for or considered to be capable of being for placement within a blood vessel without blocking flow through the vessel. As to claim 54, the plurality of surface capillary fibers are associated with at least a portion of a surface of the device with an adhesive, mechanical binding, heat bonding, or chemical bonding (lines 1-20 of page 305).

As to claim 47, Vaughn et al disclose a method for delivering an agent using a medical device. Vaughn et al disclose the medical device comprising a plurality of surface capillary fibers associated with at least a portion of a surface of the device (as disclosed in line 14 of page 304 to line 20 of page 305 and line 21 of page 308 to line 28 of page 310). See Figure 2. In lines 14-19 of page 304, Vaughn et al disclose the fibers as being polymeric fibers. In lines 1-20 of page 305, Vaughn et al disclose that a quantity of a liquid or other material for predetermined dispensing is pre-loaded and in association with the surface capillary fibers wherein the liquid or other material would be capable of eluting in a controlled way from the fibers when the surface capillary fibers are in contact with a patient's body fluids or tissue. Furthermore, each of the surface capillary fibers comprises at least one capillary along its outer surface running along at least a portion of the length of the surface capillary fiber (lines 1-20 of page 305). In line 21 of page 308 to line 28 of page 310, Vaughn et al disclose that the medical device is a

may be any of those listed on page 310 such as absorbent burn pads, bandages with bacteria barriers, medicated wound dressings, surgical sponges, or transdermal wound dressings. Even though Vaughn et al disclose that a quantity of a liquid or other material for predetermined dispensing is pre-loaded and in association with the surface capillary fibers of the medical device and that the medical device may be a medicated wound dressing or surgical sponge, Vaughn et al are silent on the specifics of the liquid or material being a bioactive agent. It would have been obvious to one having ordinary skill in the art at the time the invention was made that the liquid or other material for predetermined dispensing which is pre-loaded and in association with the surface capillary fibers as disclosed by Vaughn et al would be a medicated or bioactive agent as Vaughn et al disclose that the device may be a medicated wound dressing and thus, the liquid or other material would be a medication or bioactive agent. Even though Vaughn et al disclose that the medical device may be a medicated wound dressing or surgical sponge, Vaughn et al are silent on the specifics of contacting a patient's body fluids/tissues with the plurality of surface capillary fibers of the device and the specifics of the medical device being a percutaneous device having surface capillaries associated with a portion of the device to be placed within the patient or being an implantable device. Deker discloses a surgical dressing or sponge which is a percutaneous device or an implantable device that is adapted to be used within a patient's body in surgical operations where the dressing or sponge would contact a patient's body fluids/tissues and would be used for the application of medication within the body (lines 15-41 of column 1). It would have been obvious to one having ordinary

skill in the art at the time the invention was made that the device of Vaughn et al is a or is capable of being used as a percutaneous device or as an implantable device as taught by Deker as both Vaughn et al and Deker disclose medical devices such as medicated wound dressings and surgical sponges and Deker discloses that it is well known to use a surgical dressing or sponge within the body of a patient to apply medication. Using the device of Vaughn et al as a percutaneous device or as an implantable device as taught by Deker would result in the plurality of surface capillary fibers associated with at least a portion of a surface of the device of Vaughn et al contacting the patient's body fluids/tissues and would result in the surface capillaries of the device of Vaughn et al being associated with a portion of the device which is placed within the patient. As to claim 55, the plurality of surface capillary fibers are associated with at least a portion of a surface of the device with an adhesive, mechanical binding, heat bonding, or chemical bonding (lines 1-20 of page 305).

As to claim 57, Vaughn et al disclose a medical device comprising a plurality of surface capillary fibers associated with at least a portion of a surface of the device (as disclosed in line 14 of page 304 to line 20 of page 305 and line 21 of page 308 to line 28 of page 310). See Figure 2. In line 26 of page 303 to line 19 of page 304, Vaughn et al disclose the fibers as being polymeric fibers. In lines 1-20 of page 305, Vaughn et al disclose that a quantity of a liquid or other material for predetermined dispensing is pre-loaded into the polymer of the surface capillary fibers wherein the liquid or other material would be capable of eluting in a controlled way from the fibers when the surface capillary fibers are in contact with a patient's body fluids or tissue.

Furthermore, each of the surface capillary fibers comprises at least one capillary along its outer surface running along at least a portion of the length of the surface capillary fiber (lines 1-20 of page 305). In line 21 of page 308 to line 28 of page 310, Vaughn et al disclose that the medical device is a may be any of those listed on page 310 such as absorbent burn pads, bandages with bacteria barriers, medicated wound dressings, surgical sponges, or transdermal wound dressings. Even though Vaughn et al disclose that a quantity of a liquid or other material for predetermined dispensing is pre-loaded and in association with the surface capillary fibers of the medical device and that the medical device may be a medicated wound dressing or surgical sponge, Vaughn et al are silent on the specifics of the liquid or material being a bioactive agent. It would have been obvious to one having ordinary skill in the art at the time the invention was made that the liquid or other material for predetermined dispensing which is pre-loaded and in association with the surface capillary fibers as disclosed by Vaughn et al would be a medicated or bioactive agent as Vaughn et al disclose that the device may be a medicated wound dressing and thus, the liquid or other material would be a medication or bioactive agent. Even though Vaughn et al disclose that the medical device may be a medicated wound dressing or surgical sponge, Vaughn et al are silent on the specifics of the medical device being a percutaneous device or being an implantable device. Deker discloses a surgical dressing or sponge which is a percutaneous device or an implantable device that is adapted to be used within a patient's body in surgical operations where the dressing or sponge is used for the application of medication within the body (lines 15-41 of column 1). It would have been obvious to one having ordinary

skill in the art at the time the invention was made that the device of Vaughn et al is a or is capable of being used as a percutaneous device or as an implantable device as taught by Deker as both Vaughn et al and Deker disclose medical devices such as medicated wound dressings and surgical sponges and Deker discloses that it is well known to use a surgical dressing or sponge within the body of a patient to apply medication.

5. Claims 21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaughn et al in view of Deker as applied to claim 20 above, and further in view of Lorenz et al (U.S. Patent No. 5,156,601).

Vaughn et al in view of Deker disclose the device substantially as claimed. Even though Vaughn et al disclose the device as being products such as absorbent burn pads, bandages with bacteria barriers, medicated wound dressings, surgical sponges, or transdermal wound dressings, Vaughn et al and Deker are silent on the specifics of the bioactive agent being an anti-microbial agent. Lorenz et al disclose a wound or burn dressing in which a bioactive agent such as an anti-microbial agent has been loaded or incorporated (lines 47-68 of column 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the bioactive agent of Vaughn et al an anti-microbial agent as taught by Lorenz et al as both Vaughn et al and Lorenz et al disclose wound or burn dressings having a medicated or bioactive agent and Lorenz et al teach that it is well known to use an anti-microbial agent as the bioactive agent in the wound or burn dressings.

6. Claims 21, 24, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaughn et al in view of Deker as applied to claim 47 above, and further in view of Rothwell et al (U.S. Patent Application Publication No. 2003/0040692).

Vaughn et al in view of Deker disclose the device substantially as claimed. Even though Vaughn et al disclose the device as being products such as absorbent burn pads, bandages with bacteria barriers, medicated wound dressings, surgical sponges, or transdermal wound dressings, Vaughn et al and Deker are silent on the specifics of the bioactive agent being a growth factor. Rothwell et al disclose a wound dressing in which a bioactive agent such as an anti-microbial agent (i.e., an antibiotic) or a growth factor has been loaded or incorporated into the dressing (paragraphs [0013]-[0019]). In paragraph [0031], Rothwell et al disclose that the dressing may be used to heal a wound or damage to external tissue of a living organism or patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the bioactive agent of Vaughn et al an anti-microbial agent or growth factor as taught by Rothwell et al as both Vaughn et al and Rothwell et al disclose wound dressings having a medicated or bioactive agent and Rothwell et al teach that it is well known to use an anti-microbial agent or a growth agent as the bioactive agent in the wound dressing.

Allowable Subject Matter

7. Claim 53 is allowed.

8. Claims 22, 23, 27, 49, 50, and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

9. Applicant's arguments with respect to claims 20, 21, 24-26, 47, 54, 55, and 57 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767